

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Babich, et al.

Art Unit: 1652

Serial No: Not yet assigned

Examiner: Patterson, C.

Filed: Herewith

Attorney Docket No. BSA-7.02

For: Matrices for Drug Delivery and
Methods for Making and Using the
Same

CERTIFICATE OF EXPRESS MAILING

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February 15, 2002

Date of Signature
and of Mail Deposit
Kristen Willett

Hon. Commissioner of Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir:

This Preliminary Amendment is being filed in conjunction with a continuation filing based on U.S. Serial No. 09/503,438. Prior to substantive examination of the above-referenced patent application, please amend the application as follows:

In the specification:

Please enter the following amendments to the written description.

At page 1, section 1 "RELATED APPLICATION INFORMATION", please replace the sentence with the following:

“This application is a continuation of U.S.S.N. 09/503,438, filed February 14, 2000, which claims the benefit of priority under 35 U.S.C. section 119(e) to Provisional Application 60/119,828, filed February 12, 1999, the specifications of both of which are hereby incorporated by this reference in their entirety.”

2007445-0100

In the claims:

Please cancel claims 1 - 138, and please add claims 139 - 164:

139. A method for treating a patient with a disease, condition or deficiency, comprising (a) first administering to said patient a biocompatible matrix comprising a first encapsulated reaction center, (b) then administering to said patient a first prodrug, wherein said biocompatible matrix comprises a silica-based sol-gel matrix and said first prodrug and said biocompatible matrix treat said disease, condition or deficiency.

140. The method of claim 139, wherein said first reaction center comprises one of the following: an enzyme, an antibody or a catalytic antibody.

141. The method of claim 139, wherein reaction of said first prodrug with said first reaction center produces a biologically active agent.

142. The method of claim 139, wherein administering said biocompatible matrix comprises implantation into said patient.

143. The method of claim 139, wherein said first reaction center is substantially cell-free.

144. The method of claim 139, wherein said biocompatible matrix is immunoisulatory.

145. The method of claim 139, wherein said biocompatible matrix is prepared from at least one type of oxysilane.

146. The method of claim 143, wherein said biocompatible matrix is prepared from at least one type of oxysilane.

147. The method of claim 139, wherein said first prodrug is administered to said patient on at least more than one occasion.

148. The method of claim 139, wherein said first prodrug is administered to said patient on at least more than three occasions.

149. The method of claim 143, wherein said first prodrug is administered to said patient on at least more than one occasion.

150. The method of claim 146, wherein said first prodrug is administered to said patient on at least more than two occasions.

151. The method of claim 139, wherein said biocompatible matrix further comprises a second encapsulated reaction center.

152. The method of claim 143, wherein said first reaction center replaces, augments or supplements an endogenous biological activity.

153. A method for treating a subject suffering from a disease, deficiency or condition, comprising exposing fluids from said subject to a biocompatible, silica-based sol-gel matrix comprising a first reaction center, wherein said first reaction center provides a biological function to treat said disease, deficiency or condition of said subject.

154. The method of claim 153, wherein said biological function is naturally occurring and a deficiency in said biological function is at least in part responsible for said disease, deficiency or condition.

155. The method of claim 153, wherein said first reaction center is substantially cell-free.

156. The method of claim 153, wherein said exposure of said fluids occurs extracorporeal to said subject.

157. The method of claim 155, wherein said exposure of said fluids occurs extracorporeal to said subject.

158. The method of claim 153, wherein said first reaction center reduces the toxicity of a chemical moiety contained in said fluids.

159. The method of claim 155, wherein said first reaction center reduces the toxicity of a chemical moiety contained in said fluids.

160. The method of claim 156, wherein said first reaction center reduces the toxicity of a chemical moiety contained in said fluids.

161. The method of claim 153, wherein said first reaction center is one of the following: cytochrome P-450, hepatocytes or Kupffer cells.

162. The method of claim 153, wherein said fluids are blood of said subject.

163. The method of claim 153, wherein said biocompatible matrix further comprises a second reaction center.

164. The method of claim 153, wherein said first reaction center provides enzymatic activity in which said subject is deficient.

REMARKS

Claims 1-138 are pending and have been cancelled. New claims 139 - 164 have been added. Support for the newly added claims may be found throughout the specification and in the claims as originally filed. No new matter has been added.

Cancellation of claims should in no way be construed as an acquiescence or surrender of any originally claimed subject matter, or as narrowing any of the originally filed claims. The cancellation of the original claims and the substitution of the new claims is being made not only to point out with particularity and to claim the present invention, but also to expedite prosecution of the present application. Applicants reserve the option to prosecute further the originally filed claims, or similar ones, in the instant or a subsequent patent application.

CONCLUSION

In view of the foregoing, applicants respectfully request consideration of the claims and prompt allowance of the claims. Early and favorable consideration is respectfully solicited. The Commissioner is authorized to charge any under-payments or credit any over- payments to our Deposit Account No.06-1448. The Examiner may address any questions raised by this submission to the undersigned at 617-832-1169.

Respectfully Submitted,

Date: February 15, 2002

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Marked-up version of replacement paragraphs of the specification showing changes made:

At page 1, section 1 "RELATED APPLICATIONS", the existing sentence was deleted and the following new sentence was inserted:

“This application is a continuation of U.S.S.N. 09/503,438, filed February 14, 2000, which claims the benefit of priority under 35 U.S.C. section 119(e) to Provisional Application 60/119,828, filed February 12, 1999, the specifications of both of which are hereby incorporated by this reference in their entirety.”

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Marked-up version of the claims:

Claims 1 - 138 were cancelled, and claims 139 - 164 added, so no mark-up is provided.

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